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manufacturer also intends the product to be used for other, nonpharmacological purposes. *See, e.g., United States v. Guardian Chemical Corp.*, 410 F.2d 157, 162-163 (2d Cir. 1969) (solvent intended both to dissolve kidney stones and to clean medical instruments was properly regulated as a “drug”). Thus, if there is evidence that nicotine-containing tobacco products are intended to produce significant drug effects in consumers, the fact that manufacturers may also intend them to provide “flavor” or other nonpharmacological effects would not defeat a finding that such products are “drugs” within the meaning of the Act.

2. Philip Morris also contends that in reproducing certain quotes from Philip Morris documents, FDA omitted portions of the documents that would have shown that the author did not believe that people smoke to obtain the pharmacological effects of nicotine. Philip Morris cites four examples. FDA has reviewed each of the documents in question and has concluded that each of the statements quoted in the Jurisdictional Analysis has been fairly presented and has not been taken out of context.

First, FDA reproduced in the Jurisdictional Analysis a number of quotes from memoranda, presentations, and letters by William Dunn, a senior scientist at Philip Morris, who was responsible for a large number of research projects on smoking motivation. The quotes demonstrated that Dunn believed people smoke to obtain the pharmacological effects of nicotine. *See* 60 FR 41591, 41596–41599, 41682, 41756, 41761. Philip Morris claims that several quotes were taken out of context, and that the full context demonstrates that Dunn did not believe the pharmacological effects of nicotine are the primary reason people smoke, and in fact did not know why people smoke. Philip Morris

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also contends that the quotes attributed to Dunn were in fact the views of other scientists that Dunn was simply describing.

The collected writings of William Dunn could not be clearer. As is fully demonstrated in the Jurisdictional Analysis, he made repeated statements throughout his career reflecting a consistent belief that people smoke primarily to obtain the psychopharmacological effects of nicotine. As recently as 1994, when Dunn was visited by FDA investigators, he told them that people smoke for the nicotine.⁸¹⁸ At a conference in 1972, Dunn explained his “conviction” that consumers smoke for the pharmacological effects of nicotine. This quote also refutes Philip Morris’ claim that Dunn was merely describing the views of other scientists:

Let me explain *my conviction*.

The cigarette should be conceived not as a product but as a package. The product is nicotine. The cigarette is but one of many package layers The smoker must strip off all these package layers to get to that which he seeks Think of the cigarette pack as a storage container for a day’s supply of nicotine Think of the cigarette as a dispenser for a dose unit of nicotine Think of a puff of smoke as the vehicle of nicotine:

- 1) A convenient 35 cc mouthful contains approximately the right amount of nicotine
- 2) The smoker has wide latitude in further calibration: puff volume, puff interval, depth and duration of inhalation . . .
- 3) Highly absorbable: 97% nicotine retention
- 4) Rapid transfer: nicotine delivered to blood stream in 1 to 3 minutes

Smoke is beyond question the most optimized vehicle of nicotine.⁸¹⁹

⁸¹⁸ See notes summarizing May 10, 1994 meeting between FDA and Dunn WL. See AR (Vol. 21 Ref. 231).

⁸¹⁹ Dunn WL (Philip Morris Inc.), *Motives and Incentives in Cigarette Smoking* (1972), at 5-6 (emphasis added). See AR (Vol. 12 Ref. 133).

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Dunn further explained how he and other Philip Morris officials could both express uncertainty about “why people smoke” and believe that they smoke for the pharmacological effects of nicotine: “If we accept the premise that nicotine is what the smoker seeks, we’ve still not answered the question ‘Why do people smoke’? We’ve merely reformulated it to read ‘Why does the smoker take nicotine into his system?’”⁸²⁰

Thus, it was Dunn’s “conviction” that people smoke to obtain a systemic dose of nicotine. What remained to be determined was precisely why the pharmacological effects of nicotine were reinforcing to smokers and what biochemical mechanisms were triggered by nicotine in the central nervous system. In fact, the records of Philip Morris research between the 1960’s and the 1980’s demonstrate that Philip Morris spent those decades conducting exhaustive research to determine the physiological and psychoactive effects of nicotine inhalation that cause smokers to repeatedly seek nicotine, and to ascertain the “dose-regulating” mechanisms through which smokers obtain an adequate amount of nicotine to achieve those effects.⁸²¹ See Jurisdictional Analysis, 60 FR 41599.

Accordingly, FDA concludes that it has appropriately represented the words of William Dunn.

The second document is a 1969 speech to the board of directors of Philip Morris by Helmut Wakeham, vice president for research and development. The speech begins with the statement that scientists cannot yet give a definitive explanation of why people smoke “backed up by fact.” The speech nevertheless attempts to answer the question by

⁸²⁰ *Id.* at 6-7.

⁸²¹ See documents printed in 141 Cong. Rec. H7646-7683 (daily ed. Jul. 25, 1995), and 141 Cong. Rec. H8127-8135 (daily ed. Aug. 1, 1995). See AR (Vol. 14 Ref. 175a and Vol. 711 Ref. 6).

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marshaling three types of available evidence: what smokers say about why they smoke, what differences in personality characterize smokers and nonsmokers, and what the “immediate effects of smoke inhalation upon . . . human body function” are.⁸²² In the latter category, the speech provides a long list of nicotine’s effects on human body function, including “arousal center in brain stem excited.”⁸²³ Following this discussion of the evidence, the speech concludes with the quote cited by FDA in the Jurisdictional Analysis: “We are of the conviction, in view of the foregoing, that the ultimate explanation for the perpetuated cigaret habit resides in the pharmacological effect of smoke upon the body of the smoker, the effect being most rewarding to the individual under stress.”⁸²⁴

This document speaks for itself. It is beyond question that the quoted statement reflects the “conviction” of the author of the speech that people continue to smoke to obtain the pharmacological effects of nicotine, and that this conviction existed as a result of the available data.

The third document cited by Philip Morris provides equally weak support for the claim that Philip Morris researchers were uncertain whether people smoke to obtain nicotine. From an internal Philip Morris document entitled “Why People Start to Smoke,” FDA printed a quote from the end of the document describing the results of a “special

⁸²² Wakeham H (Philip Morris Inc.), *Smoker Psychology Research* (Nov. 26, 1969), at 9. See AR (Vol. 11 Ref. 142).

⁸²³ *Id.* at 10.

⁸²⁴ *Id.* at 11.

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study done for Philip Morris” on “the motivation that leads to a *continuation* of smoking”.⁸²⁵

[T]he circumstances in which smoking occurs may be generalized as follows:

1. As a narcotic, tranquilizer, or sedative. Smokers regularly cigarettes at times of stress.
2. At the beginning or ending of a basic activity. . . .
3. Automatic smoking behavior.⁸²⁶

Philip Morris points to a statement, from the portion of the document on why people *start* smoking, that “[t]here are surprisingly few hard facts on the question of the *initiation* of smoking,”⁸²⁷ claiming that this somehow shows that the author is unsure of why people *continue* to smoke. As the document itself demonstrates, the author describes no uncertainty on the question of why people continue to smoke.

The fourth document cited by Philip Morris is the first of several Philip Morris reports on research conducted by the company to test its hypothesis that smoking is used in times of stress as an “anxiety reducer.”⁸²⁸ The proposed study involved administering shocks to college students and determining whether stress caused the students to smoke more. According to Philip Morris, the research proposal expresses uncertainty about whether smoking mitigates stress, and therefore cannot support FDA’s conclusion that Philip Morris officials believed that nicotine’s pharmacological effects motivate smoking behavior.

⁸²⁵ Udow A (Philip Morris Inc.), *Why People Start to Smoke* (Jun. 2, 1976), in 141 Cong. Rec. H7663-H7664 (daily ed. Jul. 25, 1995) (emphasis added). See AR (Vol. 14 Ref. 175a).

⁸²⁶ *Id.* at H7664.

⁸²⁷ *Id.* at H7663 (emphasis added).

⁸²⁸ Ryan FJ (Philip Morris Inc.), *Proposed Research Project: Smoking and Anxiety* (Dec. 23, 1969), in 141 Cong. Rec. H7648 (daily ed. Jul. 25, 1995). See AR (Vol. 14 Ref. 175a).

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FDA disagrees that this document can be used to demonstrate that Philip Morris is uncertain about the relationship of smoking and stress. Because the document in question merely proposes the research to test the hypothesis that smoking reduces anxiety, it does not attempt to answer the question posed. What Philip Morris fails to point out is that this research, once begun, showed a “very high” correlation between personality factors, “particularly the Anxiety factor,” and puff rate and that the researchers were “very much encouraged by the trend of these findings.”⁸²⁹ In fact, this study design appears to have been abandoned in favor of other designs only because “fear of shock is scaring away some of our more valuable subjects.”⁸³⁰ Subsequent research reports show that Philip Morris researchers continued to obtain results showing a correlation between anxiety and both puffing and nicotine intake,⁸³¹ and subsequent statements by Philip Morris researchers continue to show that they believed that one of the primary motives for smoking is to relieve stress.⁸³²

⁸²⁹ Dunn WL (Philip Morris Inc.), *Consumer Psychology* (Sep.16-Oct. 15,1971) (discussing projects entitled, “Shock I, II, III, IV”), in 141 Cong. Rec. H7648-7649 (daily ed. Jul. 25, 1995). See AR (Vol. 14 Ref. 175a).

⁸³⁰ Dunn WL (Philip Morris Inc.), *Quarterly Report-Projects 1600 and 2302* (Oct. 5, 1972) in 141 Cong. Rec. H7649 (daily ed. Jul. 25, 1995). See AR (Vol. 14 Ref. 175a).

⁸³¹ Dunn WL (Philip Morris Inc.), *1600 Objectives for 1973* (Nov. 14, 1972) (subjects show differential heart rate when threatened with shock on days when they are allowed to smoke compared to days when they are not), in 141 Cong. Rec. H8130 (daily ed. Aug. 1, 1995) See AR (Vol. 711 Ref. 6).

Philip Morris Research Center, *Behavioral Research Annual Report* (Jul. 18, 1975), in 141 Cong. Rec. H7652, H7654 (daily ed. Jul. 25, 1995). See AR (Vol. 21 Ref. 240a-2).

⁸³² Udow A (Philip Morris Inc.), *Why People Start to Smoke* (Jun. 2, 1976) (“the circumstances in which smoking occurs may be generalized as follows: 1. As a narcotic, tranquilizer, or sedative. Smokers regularly use cigarettes at times of stress. . . .”), in 141 Cong. Rec. H7664 (daily ed. Jul. 25, 1995). See AR (Vol. 14 Ref. 175a).

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Not only do the documents discussed immediately above contradict Philip Morris' assertion that its employees do not know why people smoke, but the available Philip Morris documents contain overwhelming support for the finding that Philip Morris officials believe that the major reason people smoke is to obtain the pharmacological effects of nicotine. Expressions of this belief are repeated frequently and consistently over the period of years reflected in these documents. *See, e.g.*, Jurisdictional Analysis, 60 FR 41595–41599, 41608, 41613–41615, 41650–41652.

3. Philip Morris contends that in reproducing William Dunn's statement of his "conviction" that cigarettes are the "most optimized vehicle" for delivering nicotine, *see* comment 2, above, FDA omitted a subsequent paragraph in which the scientist attempted to defuse concern about his "drug-like conceptualization of the cigarette":

Lest anyone be made unduly apprehensive about this drug-like conceptualization of the cigarette, let me hasten to point out that there are many other vehicles of sought-after agents which dispense in dose units: wine is the vehicle and dispenser of alcohol, tea and coffee are the vehicles and dispensers of caffeine, matches dispense dose units of heat, and money is the storage container, vehicle and dose-dispenser of many things.⁸³³

Philip Morris claims that this paragraph demonstrates that the earlier part of the quote cannot be used as evidence that Philip Morris intends cigarettes as nicotine delivery systems.

FDA disagrees. The paragraph quoted by Philip Morris illustrates that tobacco company officials were aware of the potential consequences of admitting that cigarettes are "drug-like." Moreover, the paragraph does not in any way undercut the fundamental

⁸³³ Dunn WL (Philip Morris Inc.), *Motives and Incentives in Cigarette Smoking* (1972), at 6. *See* AR (Vol. 12 Ref. 133).

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point made by Dunn: that cigarettes are *nicotine* delivery systems. The fact that other items can also be conceptualized as delivery systems for various things cannot alter what it was that Dunn believed was the essential ingredient delivered by cigarettes: *doses of nicotine*. He did not conceptualize cigarettes as delivery systems for flavor, or taste, or something to occupy one's hands. Rather, he conceptualized cigarettes as delivery systems for "a dose unit of nicotine," which is "delivered to [the] blood stream in 1 to 3 minutes."⁸³⁴

4. Philip Morris also contends that in reproducing certain quotes from Philip Morris documents, FDA omitted portions of the documents that were inconsistent with the quoted portion.

First, Philip Morris contends that FDA omitted a significant passage from a quote on a proposed Philip Morris study on smoking and hyperactivity. The full quote with the omitted passages follows:

Some children are so active (or "hyperkinetic") that they are unable to sit quietly in school and concentrate on what is being taught. In recent years it has been found that amphetamines, which are strong stimulants, have the anomalous effect of quieting these children down and enabling them to concentrate in the face of distractions which otherwise would have disrupted their attention. Many children are therefore regularly administered amphetamines throughout grade school years. The wisdom of such prescription is open to question and some published reports have suggested that caffeine, in the form of coffee or tea for breakfast would produce the same end result. We wonder whether such children may not eventually become cigarette smokers in their teenage years as they discover the advantage of self-stimulation via nicotine. We have already collaborated with a local school system in identifying some such children presently in the third grade; we are reviewing the available literature on the topic; and we may propose a prospective study of this relationship. It would be good to show that smoking is an advantage to at least one

⁸³⁴ *Id.* at 5-6.

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subgroup of the population. Needless to say, we will not propose giving cigarettes to children.⁸³⁵

The full quote demonstrates that Philip Morris researchers regarded nicotine as a stimulant and proposed to study whether hyperactive youths use cigarettes, not for flavor or taste, but to self-medicate an attentional disorder. It is completely consistent with FDA's finding that Philip Morris officials believe that nicotine in cigarettes has pharmacological effects and that consumers use cigarettes to obtain those effects.

Philip Morris claims that the researchers were equating nicotine and caffeine. It is clear from this and later references to this study that Philip Morris was interested in whether nicotine is used to self-medicate hyperactivity by smokers who as children were "known to have their hyperactive or impulsive behaviors reduced by drugs (e.g., Ritalin)."⁸³⁶ If the researchers equated nicotine and caffeine, they regarded both substances as stimulant drugs that could be used to treat hyperactivity through their pharmacological effects. It is unlikely that they did equate them, however, since the same researchers had 2 years earlier demonstrated that nicotine produces a much more pronounced stimulant effect than caffeine.⁸³⁷

Philip Morris also claims that this document proposed a study on hyperkinetic adults, rather than children. Nothing in the available documents supports this claim. The documents mention only a study of hyperkinetic "children," whom Philip Morris

⁸³⁵ Dunn WL (Philip Morris Inc.), *Smoker Psychology/May 1-31, 1974* (Jun. 10, 1974), in 141 Cong. Rec. H7651 (daily ed. Jul. 25, 1995). See AR (Vol. 14 Ref. 175a).

⁸³⁶ Dunn WL (Philip Morris Inc.), *Smoker Psychology/April 1-30, 1977* (May 13, 1977), in 141 Cong. Rec. H7657 (daily ed. Jul. 25, 1995). See AR (Vol. 14 Ref. 175a).

⁸³⁷ Memorandum from Schori TR to Dunn WL, *Smoking and Caffeine: A Comparison of Physiological Arousal Effects* (May 17, 1992), at 1-2. See AR (Vol. 15 Ref. 189-7).

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researchers propose to identify and follow to establish whether they become smokers in their “teenage years.”

Second, Philip Morris contends that the context of a statement made by Helmut Wakeham that “nicotine is believed essential to cigarette acceptability” refers to its role in taste and flavor.⁸³⁸ The full text of this document contradicts Philip Morris’ argument. As explained in the Jurisdictional Analysis, 60 FR 41595, earlier in Wakeham’s presentation, he described the pharmacological effects of nicotine on smokers:

- (a) Low nicotine doses stimulate, but high doses depress functions.
- (b) Continued usage develops tolerance. . . .

In contrast to those effects, it is also recognised that smoking produces pleasurable reactions or tranquility, and that this is due at least in part to nicotine, and not entirely to the physical manipulations involved in smoking.⁸³⁹

Three pages later, under the heading “Controlled Nicotine in Filler and Smoker,”

Wakeham says:

Even though nicotine is believed essential to cigarette acceptability, a reduction in level may be desirable for medical reasons.

Problems:

1. How much nicotine reduction will be acceptable to the smoker?
2. What taste difference will be tolerated?⁸⁴⁰

The document, on its face, demonstrates two things: (1) Wakeham believed that nicotine produced pharmacological effects in smokers; and (2) the problem of determining

⁸³⁸ Wakeham H (Philip Morris Inc.), *Tobacco and Health—R&D Approach* (Nov. 15, 1961), at 43. See AR (Vol. 125 Ref. 1314).

⁸³⁹ *Id.* at 40.

⁸⁴⁰ *Id.* at 43.